ET

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,451	07/30/2003	Katia Vancompernolle	2676-6045US	5403

24247 7590 01/26/2006

TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,451	VANCOMPERNOLLE, KATIA	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,11-14 and 18-22* is/are pending in the application.

4a) Of the above claim(s) *11-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The finality of the Office Action dated 07/27/2005 has been withdrawn in view of new rejections and new grounds of rejection.

2. Claims 1, 2, 11-14, 18-22 are pending in this application. Claims 11-14 have been previously withdrawn from consideration.

Claims 1, 2, and 18-22 are under consideration in this Office Action.

3. The rejection of claim 21, 22 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of applicants' amendment filed on 10/17/2005 where the claims have been amended to recite the amino acid sequence of SEQ ID NO:1. However, new grounds of rejection under 35 U.S.C. 112, first paragraph, are presented below.

4. As stated in the previous Office Action dated 08/12/2004, acknowledgment is made of applicant's claim for foreign priority based on an application filed in the European Patent Office (EPO) on 1/31/2001, however, that applicant has not filed a certified copy of the EP 01200353.9 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 2, 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 2, the claims recite the phrase "methylglyoxal modifiying activity" which renders the claims vague and indefinite. The specification teaches a glyoxlase I enzyme from human of SEQ ID NO: 1 which catalyzes the isomerization of the hemithioacetal, produced by the nonenzymatic conjugation of methylglyoxal with glutathione, to S-D-lactoylglutathione (see specification on page 3, paragraph [0006]).

It is not clear if the recited polypeptide has any other or additional enzyme activities as encompassed by the phrase "methylglyoxal modifiying activity". Claims 18-20 are also rejected because they do not correct the defect of claim 1 or claim 2. Amending the claims to recite a glyoxalase I activity may over come the rejection.

Regarding claim 12, it is not clear as what specific modification of proteins is claimed, and it is not clear how contacting any cell with a means to phosphorylate the polypeptide comprising SEQ ID NO: 1 as recited would lead to any modulation of methylglyoxal-modification of protein in a cell. The specification teaches that TNF treatment lead to the production of proteins containing methylglyoxal and that such production of these proteins is correlated to the phosphorylation of the glyoxalase I of SEQ ID NO: 1. It is uncertain if applicants actually intend to recite that phosphorylation of the glyoxalase I of SEQ ID NO: 1 would result in the increased production of proteins having methylglyoxal. Claims 13 and 14 are also rejected because they do not correct the defect of claim 13.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 2 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are genus claims that are directed toward any phosphorylated protein comprising SEQ ID NO:1 and having any "methylglyoxal modifying activity". The scope of the claims includes many and all types of methylglyoxal modifications which is not limited to the formation of S-D-lactoylglutathione from the hemithioacetal produced by the nonenzymeatic conjugation of methylglyoxal and glutathione. The genus is highly variable because a significant number of modifying activities exists.

No patentable weight is given to the process of producing the claimed polypeptide as recited in claims 18 and 20 since there is no structural limitations from the process of producing the claimed polypeptide.

The specification discloses a human glyoxalase I consisting of the amino acid sequence of SEQ ID NO: 1. The specification teaches that the glyoxlase I enzyme of SEQ ID NO: 1 catalyzes the isomerization of the hemithioacetal, produced by the nonenzymatic conjugation of methylglyoxal with glutathione, to S-D-lactoylglutathione (see specification on page 3, paragraph [0006]). However, the specification does not describe the enzyme as having any or additional enzyme activities as encompassed by the recitation of "methylglyoxal modifiying activity".

In view of the above considerations, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of any phosphorylated protein comprising SEQ ID NO:1 and having any methylglyoxal modifying activity.

Amending the claim to recite that the polypeptide has glyoxalase I activity may overcome the rejection.

Claim Rejections - 35 U.S.C. § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 18, 19, 21, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ranganathan et al. (J Biol Chem. 1993 Mar 15;268(8):5661-7; reference of record) in view of Pestka et al. (Protein Expr Purif. 1999 Nov;17(2):203-14; reference of record).

Ranganathan et al. teach the human colon glyoxalase I which is a mammalian glyoxalase I enzyme that has an amino acid sequence that is 100 % identical to SEQ ID NO: 1 (see enclosed alignment Accession A46714) and has several potential phosphorylation sites including Ser 8, Ser 21, Ser 26, and Thr107 of SEQ ID NO:1 (see entire publication, especially Figure 2b. on p. 5664).

The claims differ from the teachings of Ranganathan et al. in that the human glyoxalase I of SEQ ID NO:1 is phosphorylated at one or more positions selected from the group consisting of Ser 8, Ser 21, Ser 26, and Thr107 of SEQ ID NO:1.

Pestka et al. teach (1) various methods for phosphorylating proteins by introducing protein kinase recognition sites into any protein and subsequent phosphorylation of the protein with radioisotopes ^{32}P or ^{33}P through the action of protein kinases or by directly phosphorylating proteins that already contain protein kinase recognition sites with radioisotopes ^{32}P or ^{33}P through the action of protein kinases, (2) the methods can be applied to virtually all proteins, (3) introduction of a kinase recognition site allows proteins to keep their essential structure intact, and (4) the advantage that these phosphorylated proteins are useful in a wide variety of applications, such as pharmocokinetics, localization, and diagnostic imaging (see entire publication, especially pp.203-206, and p.211 **Concluding Remarks**).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to phosphorylate the human glyoxalase I as taught by Ranganathan et al. using the methods for phosphorylating proteins taught by Pestka et al. to create a phosphorylated human glyoxalase I having an amino acid sequence that is 100% identical to SEQ ID NO: 1, where one or more positions selected from Ser 8, Ser 21, Ser 26, andThr107 of SEQ ID NO:1 is phosphorylated with radioisotopes ^{32}P or ^{33}P through the action of protein kinases; or a protein kinase recognition site is introduced into the said human glyoxalase I and then the said human glyoxalase I is phosphorylated with radioisotopes ^{32}P or ^{33}P through the action of protein kinases.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this so that the phosphorylated human glyoxalase I can then be used in a wide variety of applications as taught by Pestka et al. including pharmocokinetics, localization, and diagnostic imaging of the phosphorylated human glyoxalase I, and that introduction of a kinase recognition site allows proteins to keep their essential structure intact.

One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for success for making a phosphorylated human glyoxalase I because Pestka et al. teach that the stated methods for phosphorylating proteins with protein kinase recognition sites can be applied to virtually all proteins.

No patentable weight is given to the process of producing the claimed polypeptide as recited in claims 18 and 22 since there is no structural limitations from the process of producing the claimed polypeptide.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECH